IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9168

Bartle, J. November 26, 2013

Robert J. Johnson ("Mr. Johnson" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Mr. Johnson also submitted a claim for derivative benefits on behalf of his daughter, Jolene L. Johnson. The Trust, however, determined that Mr. Johnson had not submitted sufficient information on which a determination of derivative benefits could be made. It does not appear that Mr. Johnson provided the requested information. In any event, Mr. Johnson did not appeal the Trust's determination.

support his claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In March, 2008, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Allan J. Stahl, M.D., F.A.C.C., F.A.C.P. Based on an echocardiogram dated April 10, 2002, Dr. Stahl attested in Part II of Mr. Johnson's

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3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

Green Form that claimant had moderate mitral regurgitation;[4] surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™;[5] and a stroke due to (a) bacterial endocarditis contracted after use of Pondimin® and/or Redux™, or (b) chronic atrial fibrillation with left atrial enlargement as defined in Green Form Question F.5., or (c) valvular repair and/or replacement surgery that resulted in a permanent condition that meets the criteria for Functional Level

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4. Dr. Stahl also attested that claimant suffered from bacterial endocarditis associated with either mild or greater aortic regurgitation and/or moderate or greater mitral regurgitation; an abnormal left atrial dimension; a reduced ejection fraction in the range of 50% to 60%; a peripheral embolus following surgery resulting in severe permanent impairment of the kidneys, abdominal organs, or extremities; and New York Heart Association Functional Class I Symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring . . . [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a). The Trust does not contest Mr. Johnson's entitlement to Level III benefits.

IV of the AHA Stroke Outcome Classification System,[6] determined six months or later after the event.[7]

In addition, Dr. Stahl attested that claimant did not suffer from chordae tendineae rupture. Under the Settlement Agreement, the presence of chordae tendineae rupture requires the payment of reduced Matrix Benefits for a claim based on damage to the mitral valve. See Settlement Agreement § IV.B.2.d.(2)(c)ii)c).

In July, 2008, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists.[8] In

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6. Dr. Stahl also attested, at one point, that Mr. Johnson met the criteria for Functional Level III of the AHA Stroke Outcome Classification System. Under the Settlement Agreement, a claimant is entitled to Level IV benefits if he or she qualifies for Level III benefits and suffers a "stroke due to Bacterial Endocarditis contracted after use of Pondimin® and/or Redux™ or as a consequence of chronic atrial fibrillation with left atrial enlargement as defined in Section IV.B.2.c.(2)(b)(ii) [sic] which meets the criteria of AHA Stroke Outcome Classification Functional Level III, determined six months after the event." See Settlement Agreement § IV.B.2.c.(4)(a) (footnote omitted).

7. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she qualifies for Level III benefits and suffers a "severe stroke caused by aortic and/or mitral valve surgery or due to bacterial endocarditis contracted after use of Pondimin® and/or Redux™ or as a consequence of chronic atrial fibrillation with left atrial enlargement as defined in Section IV.B.2.c.(2)(b)(ii) [sic] and the severe stroke has resulted in a permanent condition which meets the criteria of AHA Stroke Outcome Classification Functional Levels IV or V, determined six months after the event." See Settlement Agreement § IV.B.2.c.(5)(b)i) (footnote omitted).

8. The Trust transmitted Mr. Johnson's claim to the auditing cardiologist as one for Level III benefits because the Trust

(continued...)

audit, Dr. Oliner concluded that there was a reasonable medical basis for Dr. Stahl's findings that claimant had moderate mitral regurgitation and surgery to replace his mitral valve. Dr. Oliner, however, determined that there was no reasonable medical basis for Dr. Stahl's Green Form representation that claimant did not have chordae tendineae rupture. In support of this conclusion, Dr. Oliner explained, "There is definite flail posterior mitral valve leaflet, which is due to chordae tendinae rupture."

Based on Dr. Oliner's findings, the Trust issued a post-audit determination that Mr. Johnson was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[9] In contest, claimant contended that he was entitled to Level V benefits as a result of his stroke. In support of this argument, Mr. Johnson submitted a number of records, including the reports of several evaluations

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8. (...continued)
determined that Mr. Johnson had not provided the required documentation to support claims for Level IV or Level V benefits.

9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Johnson's claim.

performed in connection with his application for Social Security Disability benefits and a March 6, 2009 declaration of Dr. Stahl. In his declaration, Dr. Stahl stated:

> The stroke that [Mr. Johnson] suffered in July 2007 has left him legally blind in the right eye and [claimant] states [he] "is no longer able to care for himself or be left alone because he cannot be trusted to safely cook without supervision, the stroke also has left him unable to drive and [he] has to rely on others to manage his money and do his shopping". These symptoms score Mr. Johnson on the AHA stroke outcome score of 3 with more than 2 domains impaired, severity of C in 1 or more domains and leaving him with a function level of III. He has been found to, and remains disabled by the Social Security Administration as a direct result from this stroke.

Finally, notwithstanding Dr. Stahl's earlier statement in the Green Form that claimant did not have chordae tendineae rupture, claimant asserted that the presence of chordae tendineae rupture should not reduce his Matrix Benefits because his chordae tendineae rupture was a result of his ingestion of Diet Drugs or was caused by a prior episode of bacterial endocarditis. In support, Mr. Johnson submitted various materials, including a November 4, 2008 letter from Dr. Stahl, and relied again on the March 6, 2009 declaration of Dr. Stahl. In his November 4, 2008 letter, Dr. Stahl stated, in relevant part, that:

> . . . . I have reviewed the two [echocardiograms] in question, and agree that they show posterior movement of the mitral valve into the left atrium. Mr. Johnson contends that although there is a chordal

> rupture that it is still related to heart damage from the drugs. He states that he had previous febrile illnesses which could have been subclinical episodes of endocarditis. He also contends that the chordal damage itself could have been a result of the drug's effects.
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> I feel that although it is impossible to know with assurance what was the exact cause of the cord rupture, that I have seen other patients with lesions of healed endocarditis which was never diagnosed or specifically treated. I also feel that although chordal rupture is not classically associated with anorexic drug use, that it is possible that damage from the drug enabled a preexisting condition, and hence played a role.[10]

In his March 6, 2009 declaration, Dr. Stahl stated, in relevant part, the following:

> I met with him recently to review his medical history which was unremarkable prior to Pondimin exposure that started late in 1996 with duration of approx[imately] 6 months. He presented me with a treatment summary [sic] including a history and physical and blood work that was performed prior to the weight loss therapy that was performed by Felix N Sabates Jr. MD, which noted that there were NO irregular heart sounds or murmur(s) present at that time.
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> Mr. Johnson also presented me with a copy of an echocardiogram performed in April 2002, when asked what prompted the test he stated that "sometime in late 2001 he had some dental work performed following a fracture of his 2 front teeth and then became very ill with flu-like symptoms and a high fever (approx[imately] 104-105) that lasted for

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10. Dr. Stahl subsequently advised that he reviewed echocardiograms dated April 10, 2002, July 11, 2007, and July 18, 2007 in preparing this letter.

> several weeks" he also stated that prior to this he was "never that sick before for more than a day or so" and that soon after this illness his girlfriend noticed abnormal heart sounds and night sweats off and on for months. He stated that his employer at the time was a physician and when he discussed the illness he advised him to have further testing done and prescribed and [sic] course of high dose oral antibiotics (cipro + 5 z-packs).
>
> This is a classical textbook presentation [of] bacterial endocarditis which I believe with a reasonably [sic] degree of medical certainty, was the parent cause of the chordae tendinae rupture.

Thus, Dr. Stahl now acknowledges that claimant has chordae tendineae rupture.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Oliner submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that claimant did not have chordae tendineae rupture.

The Trust then issued a final post-audit determination, again determining that Mr. Johnson was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that his claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

show cause why Mr. Johnson's claim should be paid. On August 19, 2009, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8253 (Aug. 19, 2009).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant did not submit a response to the Trust's statement of the case and thus relied only on the materials submitted during the contest phase of the audit process. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[11] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See Audit Rule 35.

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11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge- helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

The issue presented for resolution of this claim is whether Mr. Johnson has met his burden of proving that there is a reasonable medical basis for his claim for Matrix A-1, Level V benefits. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Vigilante, reviewed claimant's medical records and concluded that there was no reasonable medical basis for the attesting physician's finding that Mr. Johnson's stroke resulted in a permanent condition that meets the criteria of AHA Stroke Outcome Classification Functional Level IV or V. Specifically, Dr. Vigilante stated:

> Although the Claimant had a stroke due to bacterial endocarditis contracted after diet drug use, the Claimant's Functional Level is III based on Dr. Maningo's evaluation. The Claimant's vision and cognition had been affected by the stroke. However, motor, sensory, affect, and language were intact. Functional Level IV requires three or more areas to be affected. There is no evidence that the Claimant is unable to live alone safely. However, he does require daily help from family or community resources for

> activities such as shopping and handling finances. There is no evidence that the Claimant requires assistance with most of the instrumental activities of daily living, which is also a requirement of Functional Level IV. It should be noted that the Attesting Physician documented that the Claimant was Functional Level III more than 6 months after the event.

Dr. Vigilante also reviewed claimant's April 10, 2002 and July 18, 2007 echocardiograms and determined that each echocardiogram revealed the presence of chordae tendineae rupture. In particular, Dr. Vigilante noted with respect to claimant's April 10, 2002 echocardiogram that "[t]here was chordal rupture involving a chord attached to the posterior leaflet with partial flailing of the posterior leaflet into the left atrium during systole." With respect to claimant's July 18, 2007 echocardiogram, Dr. Vigilante observed that "[t]here was a ruptured chord and partial flailing of the posterior mitral leaflet."

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for Level IV Matrix Benefits. Under the Settlement Agreement, as noted above, a claimant may receive Level IV Matrix Benefits if he or she qualifies for Level III benefits and suffers a "stroke due to Bacterial Endocarditis contracted after use of Pondimin® and/or Redux™ or as a consequence of chronic atrial fibrillation with left atrial enlargement as defined in Section

IV.B.2.c.(2)(b)(ii) [sic] which meets the criteria of AHA Stroke Outcome Classification Functional Level III, determined six months after the event." See Settlement Agreement § IV.B.2.c.(4)(a) (footnote omitted).

The Trust does not contest that claimant qualifies for Level III benefits. Although claimant's attesting physician represented that claimant suffered a stroke due to (a) bacterial endocarditis contracted after use of Pondimin® and/or Redux™, or (b) chronic atrial fibrillation with left atrial enlargement as defined in Green Form Question F.5., or (c) valvular repair and/or replacement surgery that resulted in a permanent condition that meets the criteria for Functional Level IV of the AHA Stroke Outcome Classification System, he also submitted a page of the Green Form in which he represented claimant met the criteria only for Functional Level III of the AHA Stroke Outcome Classification System. In addition, in his March 6, 2009 declaration, Dr. Stahl stated that claimant's stroke left Mr. Johnson "with a function level of III."

The Technical Advisor reviewed claimant's medical records and confirmed that Mr. Johnson had a stroke due to bacterial endocarditis contracted after Diet Drug use. He also determined that Mr. Johnson's medical records supported a finding of Functional Level III classification. Specifically, he observed that "[t]he Claimant's vision and cognition had been

affected by the stroke. . . . There is no evidence that the Claimant is unable to live alone safely. However, he does require daily help from family or community resources for activities such as shopping and handling finances."[12] Under these particular circumstances, claimant has met his burden of establishing a reasonable medical basis for his claim for Level IV Matrix Benefits.

Claimant, however, has not established that he is entitled to Matrix A-1 benefits. In support of his claim for Matrix A-1 benefits, claimant argues that the presence of chordae tendineae rupture should not reduce his Matrix Benefits because his chordae tendineae rupture was a result of his ingestion of Diet Drugs or was caused by a prior episode of bacterial endocarditis. We disagree. The Settlement Agreement specifically provides that a claimant will receive reduced Matrix Benefits if he or she is diagnosed with specific medical conditions, including chordae tendineae rupture. See Settlement Agreement § IV.B.2.d.(2)(c)ii)c). As neither claimant nor his

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12. Dr. Vigilante also found, however, that claimant did not meet the requirements for Functional Level IV because Mr. Johnson's "motor, sensory, affect, and language were intact. Functional Level IV requires three or more areas to be affected. . . . There is no evidence that the Claimant requires assistance with most of the instrumental activities of daily living, which is also a requirement of Functional Level IV." Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34. Thus, claimant has not met his burden of establishing that he meets the requirements of a claim for Level V Matrix Benefits.

attesting physician now contests the presence of chordae tendineae rupture, the Settlement Agreement requires that Mr. Johnson's claim be reduced to Matrix B-1.[13]

Claimant's argument that he is entitled to Matrix A-1 benefits because his ingestion of Diet Drugs or his bacterial endocarditis caused his chordae tendineae rupture is misplaced. Causation is not at issue in resolving claims for Matrix Benefits. Rather, claimants are required to prove that they meet the objective criteria set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred. . . .

Mem. in Supp. of PTO No. 1415, at 51 (Aug. 28, 2000). In addition, we noted:

> . . . [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

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13. The Technical Advisor also determined that all of claimant's echocardiograms revealed the presence of chordae tendineae rupture.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true, namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the medical condition at issue. The Settlement Agreement unequivocally requires a mitral valve claim to be reduced to Matrix B-1 if the claimant suffered from chordae tendineae rupture. We must apply the Settlement Agreement as written. Accordingly, claimant's assertion as to the cause of his chordae tendineae rupture is irrelevant to the issue of whether his claim should be reduced to Matrix B-1.

For the foregoing reasons, we conclude that claimant has met his burden of proving that there is a reasonable medical basis for his claim for Matrix B-1, Level IV benefits only. Therefore, we will affirm the Trust's denial of Mr. Johnson's claim Matrix A-1 benefits as well as his claim for Level V Matrix Benefits, but will reverse the trust's denial of Mr. Johnson's claim for Matrix B-1, Level IV benefits.